



NOV 24 2009

George W. Johnston
Hoffmann-La Roche Inc.
Patent Law Department
340 Kingsland Street
Nutley, New Jersey 07110

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,583,272

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,583,272, which claims the human biologic product MIRCERA® (methoxy polyethylene glycol-epoetin beta), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 445 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 445 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 10, 2009, (74 Fed. Reg. 6637), would be 1,090 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,565 - 535) + 575 \\ &= 1,090 \text{ days (3.0 years)}\end{aligned}$$

Since the regulatory review period began January 6, 2002, before the patent issued (June 24, 2003), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From January 6, 2002, to and including June 24, 2003, is 535 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,090 days, would extend the patent from August 26, 2020 to August 21, 2023, which is beyond the 14-year limit (the approval date is November 14, 2007, thus, the 14 year limit is November 14, 2021). The period of extension is limited to 445 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from

its original expiration date, August 26, 2020, to and including, November 14, 2021, or 445 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,583,272
Granted:	June 24, 2003
Original Expiration Date ¹ :	August 26, 2020
Applicant:	Pascal Sebastian Bailon
Owner of Record:	Hoffmann-La Roche Inc.
Title:	Erythropoietin Conjugates
Product Trade Name:	MIRCERA® (methoxy polyethylene glycol-epoetin beta)
Term Extended:	445 days
Expiration Date of Extension:	November 14, 2021

¹Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Tili
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: MIRCERA® (methoxy
polyethylene glycol-epoetin beta)
Docket No.:

Attention: Beverly Friedman